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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
POUS, NATALIE R	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/624,848	GERBI ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/30/03*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *32 and 33* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/20/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-31, drawn to apparatus, group 1, classified in class 606, subclass 108.

II. Claims 31-32, drawn to method of use, group 2, classified in class 606, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

Groups 1 and 2 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case (2), the apparatus is capable of being used with fewer than two incisions, or a single natural body opening. In addition, the apparatus could be used for a non-surgical procedure such as to gain tool access to a sealed chamber, or for a plumbing procedure.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group 2, restriction for examination purposes as indicated is proper.

During a telephone conversation with Attorney Frank Nguyen on August 30, 2005 a provisional election was made with traverse to prosecute the invention of the apparatus, claims 1-31. Affirmation of this election must be made by applicant in

replying to this Office action. Claims 32-33 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.
It is noted that during the telephone conversation with Attorney Frank Nguyen, claims 32-33 may be prosecuted in a future divisional application.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "412.1" has been used to designate both open ends of the tool guide. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Based on the specification, the examiner will read distal open end item "412.1" as item --412.2--.

Figure 3 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract should avoid legal language such as “enable” and “comprises.” In addition, the abstract is of undo length. Abstract should not exceed 150 words. Please make corrections accordingly.

Claim Rejections - 35 USC § 112

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 discloses the outer diameter of the tubular portion falling in the range of about 3mm to 12mm. Claim 6 is dependent on claim 5 and discloses the diameter of the same item as between about 6mm to 16mm. It is unclear which dimension should be considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bonutti (US 5320611).

Regarding Claim 1, Bonutti discloses an expandable cannula for instrument passage of similar size and shape as disclosed tool guide, and is therefore capable of guiding an end effector of a robotically controllable surgical instrument from a position outside a patient body to a position in close proximity to a surgical site within the patient body. Bonutti teaches:

A guide body (12);

A seat formation on the guide body (12), (It is noted that based on the specification, seat formation is defined as a continuous portion of the guide body formation);

A sheath formation (18) defining a passage (20) an inlet leading into the passage (14) and an outlet leading from the passage (20).

Regarding Claim 2, Bonutti teaches a sheath formation comprising a round cylindrical tubular portion (18) where passage (20) is defined within the tubular portion.

Regarding Claim 3, Bonutti discloses a tubular portion with an axially extending circumferential inner surface defining at least part of the passage (12), the diameter falling in the range of 3mm and 20mm (paragraph 3, proximate lines 40-55).

Regarding Claim 4, Bonutti discloses a tubular diameter falling in the range of 5mm and 12mm (Column 3, proximate lines 40-55).

Regarding Claims 5 and 6, Bonutti discloses tubular portion thickness varying based on selected guide wire gauge, therefore varying the outer diameter. It is suggested that a large wire has a diameter of .025 inches (Column 2, proximate lines 50-60), 0.635 mm, adding minimal diameter to the inner diameter, and still falling in the disclosed range of 3 mm to 16 mm.

Regarding Claim 7, Bonutti discloses a stop formation on the guide body (14)

Regarding Claim 8, Bonutti discloses a seat formation wherein a seat formation is defined as a portion of the tubular guide body (18).

Regarding Claim 9, Bonutti discloses a stop flange protruding radially outwardly from the round cylindrical tubular portion (14).

Regarding Claim 10, Bonutti discloses a seat formation being a portion of sheath formation (18).

Regarding Claim 11, Bonutti discloses a length extending between the stop an the opposed end of the sheath formation falling in the range between about 25mm and 250mm (Column 3, proximate lines 44-53).

Regarding Claim 16, Bonutti disclose the sheath material as elastic (Column 2, proximate lines 35-40).

Regarding Claim 17, Bonutti teaches the cannula can be made of a plurality of useful sizes, with lengths ranging from 90mm –160 mm.

Claims 18-23 and 25-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Honkanen.

Regarding Claim 18, Honkanen teaches a tool guide comprising:

An elongate body (15) defining opposed ends and a passage extending longitudinally along the body between the opposed ends (40). Honkanen discloses an instrument guide of similar size and shape as disclosed and is therefore capable of being mounted in an aperture leading into a patient body while coupled to a robotic arm.

Regarding claim 19, Honkanen discloses an engaging formation (15) comprising a socket formation (40).

Regarding Claim 20, Honkanen discloses the socket formation as the within the passage of the tool guide (5).

Regarding Claim 21, Honkanen discloses a tool guide, which comprises an inlet which leads into passage (4) being arranged to be accessible from outside the patient body when mounted in the aperture, with the socket adjacent to the inlet and an outlet leading from the passage arranged to be positioned within the patient body when the tool guide is mounted on the patient body.

Regarding Claim 22, Honkanen discloses a circumferentially extending surface defining at least part of the passage, the surface tapering radially inwardly in a direction away from the inlet (Figure 1).

Regarding Claim 23, Honkanen discloses an outer surface with at least one gripping formation (35) to be gripped by tissue when the tool guide is mounted onto the patient body.

Regarding Claim 25, Honkanen discloses a plurality of ribs (35) extending around the outer surface.

Regarding Claim 26, Honkanen discloses a sealing formation (70) to permit an instrument (100) of similar size and shape as the engaging formation of a robotic arm to pass therethrough.

Regarding Claims 27 and 28, the sealing formation is at least partially formed from a synthetic plastic such as silicone (Column 3, proximate lines 45-55).

Regarding Claim 29, Honkanen discloses an obvious change would be to line passage (40) with a metallic liner near the bottom end of the cannula for use as a drilling device.

Claims 1-2, 7-10, 12-15, 18-22, 30 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by Wright (US 6726699).

Regarding Claim 1, Wright discloses an instrument guide for surgical instrument passage of similar size and shape as disclosed tool guide, and is therefore capable of guiding an end effector of a robotically controllable surgical instrument from a position outside a patient body to a position in close proximity to a surgical site within the patient body. Wright teaches:

A guide body (38);

A seat formation on the guide body (38), (It is noted that based on the specification, seat formation is defined as a continuous portion of the guide body formation);

A sheath formation (32) defining a passage (34) an inlet leading into the passage and an outlet leading from the passage.

Regarding Claim 2, Wright teaches a sheath formation comprising a round cylindrical tubular portion (38) where passage (34) is defined within the tubular portion.

Regarding Claim 7, Wright discloses a stop formation on the guide body (24')

Regarding Claim 8, Wright discloses a seat formation wherein a seat formation is defined as a portion of the tubular guide body (38).

Regarding Claim 9, Wright discloses a stop flange protruding radially outwardly from the round cylindrical tubular portion (24').

Regarding Claim 10, Wright discloses a seat formation being a portion of sheath formation (32).

Regarding Claim 12, Wright teaches the tubular portion of the sheath formation (38) is separate from the seat formation (26) and the sheath formation is axially displaceably received in the round cylindrical tubular portion defining the seat formation (Column 2, proximate lines 35-45).

Regarding Claims 13 and 14, Wright teaches a sheath stop on instrument guide round cylindrical tubular portion of the sheath formation (24) where the sheath stop comprises a sheath flange.

Regarding Claim 18, Wright teaches a tool guide comprising:

An elongate body defining opposed ends and a passage extending longitudinally along the body between the opposed ends (24); and an engaging formation arranged to cooperate with robotic surgical system (10) including robotic arm (16).

Regarding Claim 19, Wright discloses an engaging formation comprising a socket formation (34).

Regarding Claim 20, Wright discloses the socket formation as the within the passage of the tool guide (34).

Regarding Claim 21, Wright discloses a tool guide, which comprises an inlet which leads into passage (34) being arranged to be accessible from outside the patient body when mounted in the aperture, with the socket adjacent to the inlet and an outlet leading from the passage arranged to be positioned within the patient body (14) when the tool guide is mounted on the patient body.

Regarding Claim 22, Wright discloses a circumferentially extending surface defining at least part of the passage, the surface tapering radially inwardly in a direction away from the inlet (42).

Regarding Claim 30, Wright discloses a cross-sectionally tubular portion at the outlet (32).

Regarding Claim 31, Wright discloses a wall tapering radially outwardly in a rewarward direction from the outlet (44).

Claims 18-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Ciccolella (US 6224608).

Regarding Claim 18, Ciccolella teaches a tool guide comprising:

An elongate body (68) defining opposed ends and a passage extending longitudinally along the body between the opposed ends (Figure 5c). Ciccolella discloses an instrument guide of similar size and shape as disclosed and is therefore capable of being mounted in an aperture leading into a patient body while coupled to a robotic arm.

Regarding claim 19, Ciccolella discloses an engaging formation (68) comprising a socket formation.

Regarding Claim 20, Ciccolella discloses the socket formation as the within the passage of the tool guide (10).

Regarding Claim 21, Ciccolella discloses a tool guide, which comprises an inlet which leads into passage being arranged to be accessible from outside the patient body when mounted in the aperture, with the socket adjacent to the inlet and an outlet leading from the passage arranged to be positioned within the patient body when the tool guide is mounted on the patient body.

Regarding Claim 22, Ciccolella discloses a circumferentially extending surface defining at least part of the passage, the surface tapering radially inwardly in a direction away from the inlet (72).

Regarding Claim 23, Ciccolella discloses an outer surface with at least one gripping formation (12) to be gripped by tissue when the tool guide is mounted onto the patient body.

Regarding Claim 24, Ciccolella discloses at least one gripping formation comprising a rib (12) extending helically around the outer surface.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, except 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NRP

GLENN K. DAWSON
PRIMARY EXAMINER